

1 What is claimed is:

2

3 1. In a stented graft that can alternately include a compact configuration having
4 a first diameter and an expanded configuration having a greater diameter,
5 comprising, in combination:

6 ☐ at least one stent formed in a generally cylindrical shape having an
7 outer surface and a hollow bore extending longitudinally therethrough,
8 wherein said stent can alternately exist in a compact configuration
9 having a first diameter, and an expanded configuration having a
10 greater diameter and a plurality of lateral openings; and,

11 ☐ a flexible, porous, biocompatible tubular elastomer covering having a
12 first end, a second end, an outer surface and a hollow bore that
13 extends longitudinally therethrough to define an inner surface;

14 said stent being deployed coaxially within said hollow bore of said covering
15 such that said inner surface of said tubular covering is in contact with said
16 outer surface of said stent;

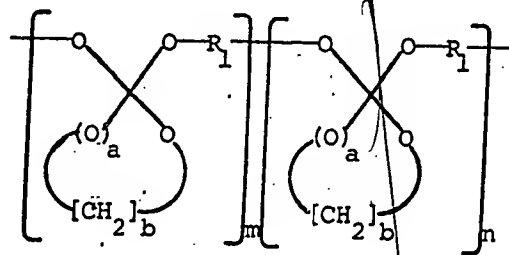
17 the improvement wherein said stent is coated with a coat comprising a
18 composite of at least one polymer and at least one therapeutic substance to
19 form a drug eluting stented graft.

20

21 2. The drug eluting stented graft of claim 1, wherein said at least one
22 polymer is a biocompatible, pharmaceutically acceptable, bioerodible
23 polymer.

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- 1 3. The drug eluting stented graft of claim 1, wherein said at least one
2 polymer is a polyester.
- 3
- 4 4. The drug eluting stented graft of claim 1, wherein said at least one
5 therapeutic agent is selected from the group consisting of antiplatelet
6 agents, anticoagulant agents, antimetabolic agents, vasoactive agents,
7 nitric oxide releasing agents, anti-inflammatory agents, antiproliferative
8 agents, antisense agents, pro-endothelial agents, anti-migratory agents,
9 antimicrobial agents, selective gene delivery vectors, sirolimus,
10 actinomycin-D and paclitaxel.
- 11
- 12 5. The drug eluting stented graft of claim 4, wherein said selective gene
13 delivery vectors are Semliki Forest Virus (SMV) adapted to deliver
14 restenosis preventing genes.
- 15
- 16 6. The drug eluting stented graft of claim 1, wherein said at least one
17 polymer is a hydrophobic, bioerodible, copolymer comprising mers I and
18 II according to the following formula:

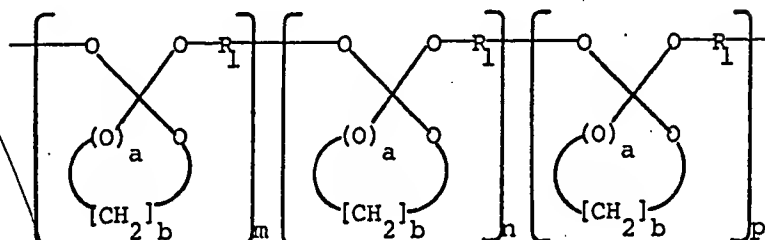


23 wherein:

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- 1 □ R_1 is a member selected from the group consisting of alkylene
2 of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6
3 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons
4 substituted with a member selected from the group consisting of alkyl of
5 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10
6 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7
7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1
8 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons,
9 and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an
10 alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to
11 10 carbons, an alkenyl of 2 to 7 carbons; and wherein a is 0 to 1; b is 2
12 to 6; m is greater than 10; n is greater than 10; and at least one of
13 R_1 , a, and b in mer I is different than R_1 , a, and b in mer II; and wherein:
14
15 □ said composite of at least one polymer and at least one therapeutic
16 substance when in operation bioerodes and releases said at least one
17 therapeutic substance at a rate selected from (1) a zero order rate, (2) a
18 continuous rate, and (3) a variable rate, which rate is produced by
19 preselecting said composite of at least one polymer and at least one
20 therapeutic substance, and said elastomer to give the desired result.
21

7. The drug eluting stented graft of claim 1, wherein said at least one polymer is a hydrophobic, bioerodible, terpolymer comprising mers I, II, and III according to the following formula:



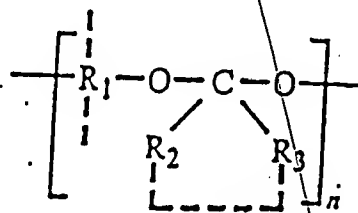
wherein:

- R₁ is a member selected from the group consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with a member selected from the group consisting of alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, an alkenyl of 2 to 7 carbons; and
- wherein a is 0 to 1; b is 2 to 6; m is greater than 10; n is greater than 10; p is greater than 10; and at least one of R₁, a, and b in mers I, II and III is different than R₁, a, and b in mers I, II and III; and wherein:

- 1 □ said composite of at least one polymer and at least one therapeutic
2 substance when in operation bioerodes and releases said at least one
3 therapeutic substance at a rate selected from (1) a zero order rate,(2)
4 a continuous rate, and (3) a variable rate, which rate is produced by
5 preselecting said composite of said at least one polymer and said at
6 least one therapeutic substance, and said elastomer to give the
7 desired result.

8
9 8. The drug eluting stented graft of claim 1, wherein:

- 10 □ a multiplicity of microcapsules is dispersed within said at least one
11 polymer, wherein said microcapsules have a wall formed of a drug
12 release rate controlling material;
13 □ said at least one therapeutic substance is contained within said
14 multiplicity of microcapsules; and,
15
16 □ said at least one polymer has the formula:



22 wherein R₁ is a member selected from the group of divalent, trivalent and
23 tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of

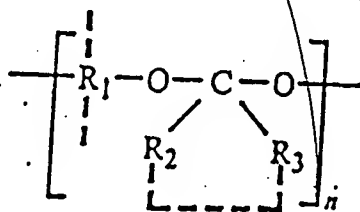
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2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons; R_2 and R_3 are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa; OR_1O with R_1 as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and alkenyl of 2 to 7 carbons formed when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said R_2 and R_3 is a member selected from the group consisting of alkoxy, alkenyloxy and OR_1O ; R_2

1 and R₃ when taken together are a member selected from the group of
2 heterocyclic and fused polycyclic rings having at least one oxygen atom in
3 the ring; and wherein n is greater than 10;
4 so that, in operation, said polymer and said microcapsules bioerode at a
5 controlled and continuous rate over a prolonged period of time, thereby releasing
6 said at least one therapeutic substance at a controlled and continuous rate over
7 a prolonged period of time.

8
9 9. The drug eluting stented graft of claim 1, wherein:

- 10 □ said coat further comprises at least a first layer and a second layer,
11 wherein said first layer comprises said at least one therapeutic
12 substance and at least a first polymer, and said second layer
13 comprises said at least one therapeutic substance and at least a
14 second polymer, wherein at least one of said first polymer and said
15 second polymer are selected from the group consisting of polymers of
16 the formula:



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1 wherein R_1 is a member selected from the group of divalent, trivalent and
2 tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to
3 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons;
4 cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7
5 carbons, alkoxy of 1 to 7 carbons, alkylene of 1 to 10 carbons, and an
6 alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons;
7 cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7
8 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and
9 an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an
10 alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2
11 to 7 carbons; R_2 and R_3 are selected from the group consisting
12 of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7
13 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons;
14 alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy
15 of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons;
16 aralkenyleneoxy of 8 to 12 carbons; oxa; $O R_1 O$ with R_1 as
17 defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms
18 formed when R_2 and R_3 are taken together; a heterocyclic ring of
19 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7
20 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons
21 formed when R_2 and R_3 are taken together; a fused polycyclic
22 ring of 8 to 12 carbon and oxygen atoms formed when R_2 and R_3
23 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen

1 atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7
2 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said
3 R_2 and R_3 is a member selected from the group consisting of alkoxy, alkenyloxy
4 and OR_1O ; R_1 and R_3 when taken together are a member selected from the
5 group of heterocyclic and fused polycyclic rings having at least one oxygen atom
6 in the ring; and wherein is greater than 10;
7 so that when in operation, said layers bioerode at a controlled and continuous
8 rate over a prolonged period of time, thereby releasing said at least one
9 therapeutic substance at a controlled and continuous rate over a prolonged
10 period of time.

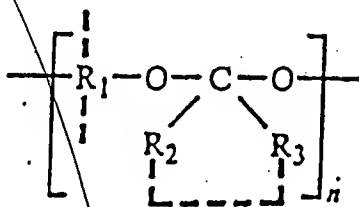
11
12 10. The drug eluting stented graft of claim 9, wherein said first polymer is a
13 pharmaceutically acceptable biocompatible non-bioerodible polymer that
14 sequesters an agent for brachytherapy.

15
16 11. The drug eluting stented graft of claim 10, wherein said agent for
17 brachytherapy is selected from the group consisting of palladium-103 (^{103}Pd),
18 ^{192}Ir , ^{32}P , ^{188}Re , and Sr/Y90 source trains.

19
20 12. The drug eluting stented graft of claim 1, wherein:

- 21 ☐ a multiplicity of discrete, closed cells exists within said at least one
22 polymer, said cells having a wall formed and defined by said at least
23 one polymer;

□ said at least one polymer has the formula:



wherein R_1 is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons; R_2 and R_3 are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa;

1 OR₁O with R₁ as defined above; a heterocyclic ring of 5 to 8 carbon and
2 oxygen atoms formed when R₂ and R₃ are taken together; a heterocyclic
3 ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7
4 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons
5 formed when R₂ and R₃ are taken together; a fused polycyclic ring of 8 to
6 12 carbon and oxygen atoms formed when R₂ and R₃ are taken together;
7 a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted
8 with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl
9 of 2 to 7 carbons; and wherein at least one of said R₂ and R₃ is a member
10 selected from the group consisting of alkoxy, alkenyloxy and OR₁O; R₂
11 and R₃ when taken together are a member selected from the group of
12 heterocyclic and fused polycyclic rings having at least one oxygen atom in
13 the ring; and wherein n is greater than 10;

14 □ wherein said at least one therapeutic substance dissolved in a
15 pharmaceutically acceptable carrier that is a solvent for said at least
16 one therapeutic substance and a nonsolvent for said at least one
17 polymer is contained within said multiplicity of discrete, closed cells;
18 so that, when in operation, said at least one polymer is capable of bioeroding at a
19 controlled and continuous rate over a prolonged period of time, thereby releasing
20 said at least one therapeutic substance at a controlled and continuous rate over
21 a prolonged period of time.

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1 13. The drug eluting stented graft of claim 1, wherein said stent comprises a
2 plurality of elements, wherein each said element comprises an undulating
3 linear shape formed into a generally cylindrical configuration having a cylinder
4 axis generally aligned on the axis of said hollow bore, and wherein each said
5 element is connected to an adjacent neighbor element by at least one linear
6 connector.

7
8 14. The drug eluting stented graft of claim 1, wherein said plurality of elements
9 comprises a spiral.

10
11 15. The drug eluting stented graft of claim 1, wherein at least one said connector
12 is substantially circumferentially offset from an adjacent neighbor connector.

13
14 16. The drug eluting stented graft of claim 15, wherein said circumferentially
15 offset connectors form a helical array.

16
17 17. The drug eluting stented graft of claim 1, wherein at least one said connector
18 is not substantially circumferentially offset from an adjacent neighbor
19 connector.

20
21 18. The drug eluting stented graft of claim 1, wherein said undulating linear shape
22 is a generally zigzag shape comprising a plurality of zigs having tips and a
23 plurality of zags having tips, wherein said tip of each said zig of each element

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1 and the nearest said tip of each said zig of an adjacent neighbor element
2 generally lie in a plane passing through the axis of said hollow bore, and
3 wherein said tip of at least one said zig of each element and at least one said
4 nearest said tip of a zig of an adjacent neighbor are connected by one said
5 linear connector.

6

7 19. The drug eluting stented graft of claim 1, wherein said undulating linear shape
8 is a sinusoidal shape having a plurality of peaks and a plurality of valleys,
9 wherein each said peak of each element and each said valley of an adjacent
10 neighbor lie generally in a common plane passing through the axis of said
11 hollow bore, and wherein at least one said peak of each element and said
12 valley of an adjacent neighbor lying generally in said common plane are
13 connected by one said linear connector.

14

15 20. The drug eluting stented graft of claim 1, wherein each said linear connector
16 has a length dimension generally parallel to the axis of said hollow bore, and
17 a width and depth dimension, and wherein said length dimension is greater
18 than said width dimension and said length dimension is greater than said
19 depth dimension.

20

21 21. The drug eluting stented graft of claim 20, wherein said length dimension is
22 about 3 to 10 times greater than said width dimension, and said length
23 dimension is about 3 to 10 times greater than said depth dimension.

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2 22. The drug eluting stented graft according to claim 1, wherein said stent and
3 said elastomer are anchored to each other by means for anchoring.

4

5 23. The tubular drug eluting stented graft according to claim 22, wherein said
6 means for anchoring comprise protrusions of said covering that fixedly
7 protrude into said lateral openings in said stent.

8

9 24. The drug eluting stented graft of claim 1 wherein said elastomer covering is
10 formed of an elastomer selected from the group consisting of
11 polytetrafluoroethylene, fluorinated ethylene propylene,
12 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl
13 chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other
14 biocompatible plastics.

15

16 25. The drug eluting stented graft of claim 1 wherein said elastomer covering is
17 formed of expanded, sintered PTFE tape, said tape having been wound about
18 the outer surface of said stent to create said covering thereon.

19

20 26. The drug eluting stented graft of claim 24, wherein said
21 polytetrafluoroethylene is expanded polytetrafluoroethylene having fibrils.

22

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1 27. The drug eluting stented graft of claim 26, wherein said fibrils measure up to
2 about 300 μ in length.

3
4 28. The drug eluting stented graft of claim 26, wherein said fibrils measure up to
5 about 200 μ in length.

6
7 29. The drug eluting stented graft of claim 26, wherein said fibrils measure up to
8 about 100 μ in length.

9
10 30. The drug eluting stented graft of claim 26, wherein said fibrils measure up to
11 about 50 μ in length.

12
13 31. The drug eluting stented graft of claim 26, wherein said fibrils measure up to
14 about 5 μ in length.

15
16 32. The drug eluting stented graft of claim 25 wherein said tape has a width of
17 less than about 1 inch.

18
19 33. The drug eluting stented graft of claim 25 wherein said tape has a thickness
20 of less than 0.015 inch (0.038 cm.) and wherein said tape is wound about
21 said stent in overlapping fashion, such that said elastomer covering
22 comprises 1 to 10 layers of said tape.

23

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1 34. The drug eluting stented graft of claim 25 wherein said tape is helically
2 wrapped about said stent.

3
4 35. The drug eluting stented graft of claim 25 wherein said tape has a width of 0.5
5 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8
6 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said drug
7 eluting stented graft.

8
9 36. The drug eluting stented graft of claim 25 wherein said tape is helically
10 wrapped alternately in a first direction and then in the opposite direction.

11
12 37. The drug eluting stented graft of claim 36 further comprising 8 layers of said
13 tape.

14
15 38. The drug eluting stented graft of claim 1 wherein said stent is a self-
16 expanding stent.

17
18 39. The drug eluting stented graft of claim 38, wherein said self-expanding stent
19 comprises a shape memory alloy that can alternately exist in a first and a
20 second crystalline state, wherein said stent assumes a radially expanded
21 configuration when said shape memory alloy is in said first crystalline state,
22 and a radially compact configuration when said shape memory alloy is in said
23 second crystalline state.

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2 40. The drug eluting stented graft of claim 1 wherein said stent is a pressure-
3 expandable stent.

4

5 41. The drug eluting stented graft of claim 1 wherein said stent is formed of a
6 metal alloy comprising at least two elements selected from the group
7 consisting of iron, cobalt, chromium, nickel, titanium, niobium, and
8 molybdenum.

9

10 42. The drug eluting stented graft of claim 39 wherein said shape memory alloy
11 comprises at least about 51% to about 59% nickel and the remainder
12 comprising titanium.

13

14 43. The drug eluting stented graft of claim 39 wherein said shape memory alloy
15 comprises about 0.25% chromium, at least about 51% to about 59% nickel,
16 and the remainder comprising titanium.

17

18 44. The drug eluting stented graft of claim 1 wherein said covering has a
19 thickness of less than 0.1 inch (0.25 cm.).

20

21 45. The drug eluting stented graft of claim 25 wherein said PTFE tape has a
22 thickness of less than 0.015 inches (0.038 cm.), said tape being wrapped
23 about said stent in overlapping fashion so as to form said covering.

FOIA b 7 - DATED 11/15/04

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2 46. The drug eluting stented graft of claim 25 wherein said PTFE tape has a
3 density of less than 1.6 g/cc.

4

5 47. The drug eluting stented graft of claim 25 wherein said covering has a
6 thickness of less than 0.1 inch (0.25 cm.) and said PTFE tape has a density
7 of less than 1.6 g/cc.

8

9 48. The drug eluting stented graft of claim 1 wherein said composite coating was
10 applied to said stent by the steps of:

- 11 ☐ immersing said stent in a liquid dispersion of said composite;
- 12 ☐ removing said stent from said liquid dispersion of said composite; and,
- 13 ☐ drying said liquid dispersion of said composite that has remained on
14 said stent,

15 whereby said composite coating is formed on said stent.

16

17 49. The drug eluting stented graft of claim 1 wherein said composite coating is
18 formed by electron beam deposition.

19

20 50. The drug eluting stented graft of claim 1 wherein said tubular covering is
21 adherent to said coat.

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1 51. A method for the treatment of cardiovascular disease, comprising implanting
2 the drug eluting stented graft of claim 1 in a patient in need of such treatment
3 wherein said implantation is effective to ameliorate one or more of the
4 symptoms of said cardiovascular disease.

5
6 52. An article of manufacture, comprising packaging material and the drug eluting
7 stented graft of claim 1 contained within the packaging material, wherein said
8 drug eluting stented graft is effective for implantation in a patient afflicted with
9 cardiovascular disease, and the packaging material includes a label that
10 indicates that said device is effective for said implantation.

11
12 53. In a tubular stented graft which is alternately deployable in a radially compact
13 configuration having a first diameter and a radially expanded configuration
14 having a second diameter, said stented graft comprising:

- 15 • a stent comprising:
- 16 □ at least one member formed in a generally cylindrical shape having
 - 17 an outer surface and a hollow bore which extends longitudinally
 - 18 therethrough to define an inner surface;
 - 19 □ said stent being initially radially collapsible to a diameter which is
 - 20 substantially equal to said first diameter of the stented graft, and
 - 21 subsequently radially expandable to a diameter which is
 - 22 substantially equal to said second diameter of the stented graft;
 - 23 and,

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- 1 □ a plurality of lateral openings existing in said stent when said stent is at
2 its radially expanded second diameter;
- 3 • a continuous, tubular PTFE covering formed on said stent, said PTFE
4 covering comprising:
- 5 □ a tubular inner base graft formed of expanded, sintered PTFE, said
6 tubular base graft having an outer surface and an inner surface, said
7 tubular base graft being deployed coaxially within the hollow bore of
8 said stent such that the outer surface of the tubular base graft is in
9 contact with the inner surface of the stent, and the inner surface of said
10 tubular base graft thereby defining a luminal passageway through the
11 stented graft; and,
- 12 □ a tubular outer layer formed of expanded, sintered PTFE tape which
13 has a width of less than about 1 inch, said tape having been wound
14 about the outer surface of said stent to create said tubular outer layer
15 thereon, such that said stent is captured between said outer layer and
16 said tubular base graft;
- 17 said tubular outer layer being attached to said tubular base graft, through
18 said lateral openings in said stent, to thereby form an integrally stented,
19 continuous PTFE tube which is alternately disposable in said radially
20 compact configuration of said first diameter and said radially expanded
21 configuration of said second diameter;

FOIA b 7 - DATED 11/15/00

1 the improvement wherein said stent is coated with a coat comprising a
2 composite of at least one polymer and at least one therapeutic substance
3 to form a drug eluting stented graft.

4
5 54. The drug eluting stented graft of claim 53, wherein said at least one
6 polymer is a biocompatible, pharmaceutically acceptable, bioerodible
7 polymer.

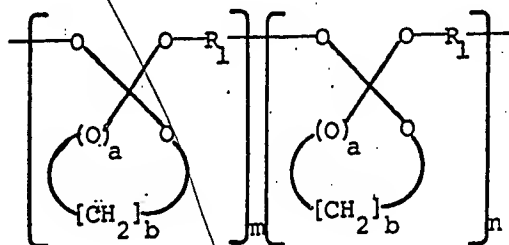
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9 55. The drug eluting stented graft of claim 53, wherein said at least one
10 polymer is a polyester.

11
12 56. The drug eluting stented graft of claim 53, wherein said at least one
13 therapeutic agent is selected from the group consisting of antiplatelet
14 agents, anticoagulant agents, antimetabolic agents, antisense agents,
15 vasoactive agents, nitric oxide releasing agents, anti-inflammatory agents,
16 antiproliferative agents, pro-endothelial agents, anti-migratory agents,
17 antimicrobial agents, selective gene delivery vectors, sirolimus,
18 actinomycin-D and paclitaxel.

19
20 57. The drug eluting stented graft of claim 56, wherein said selective gene
21 delivery vectors are Semliki Forest Virus (SMV) adapted to deliver
22 restenosis preventing genes.
23

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58. The drug eluting stented graft of claim 53, wherein said at least one polymer is a hydrophobic, bioerodible, copolymer comprising mers I and II according to the following formula:

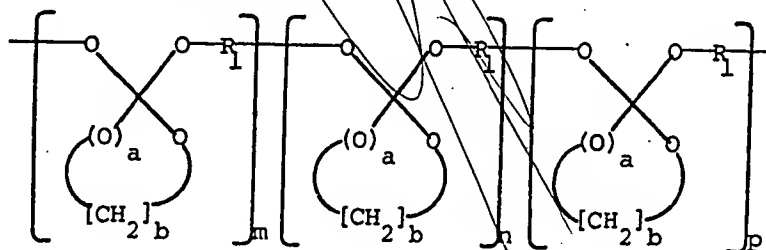


wherein:

- R_1 is a member selected from the group consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with a member selected from the group consisting of alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, an alkenyl of 2 to 7 carbons; and wherein a is 0 to 1; b is 2 to 6; m is greater than 10; n is greater than 10; and at least one of R_1 , a , and b in mer I is different than R_1 , a , and b in mer II; and wherein:

- 1 □ said composite of at least one polymer and at least one therapeutic
 2 substance when in operation bioerodes and releases said at least one
 3 therapeutic substance at a rate selected from (1) a zero order rate, (2) a
 4 continuous rate, and (3) a variable rate, which rate is produced by
 5 preselecting said composite of at least one polymer and at least one
 6 therapeutic substance, and said elastomer to give the desired result.

7
 8 59. The drug eluting stented graft of claim 53, wherein said at least one polymer
 9 is a hydrophobic, bioerodible, terpolymer comprising mers I, II, and III
 10 according to the following formula:



12 wherein:

- 13 □ R₁ is a member selected from the group consisting of alkylene of 1 to
 14 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6
 15 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7
 16 carbons substituted with a member selected from the group consisting
 17 of alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to
 18 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7
 19 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of
 20 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10
 21 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene

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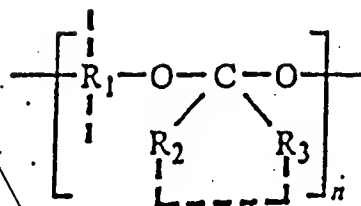
1 substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons,
2 an alkylene of 1 to 10 carbons, an alkenyl of 2 to 7 carbons; and
3 wherein a is 0 to 1; b is 2 to 6; m is greater than 10; n is greater than
4 10; p is greater than 10; and at least one of R₁, a, and b in mers I, II
5 and III is different than R₁, a, and b in mers I, II and III; and wherein:

- 6
- 7 □ said composite of at least one polymer and at least one therapeutic
8 substance when in operation bioerodes and releases said at least one
9 therapeutic substance at a rate selected from (1) a zero order rate, (2)
10 a continuous rate, and (3) a variable rate, which rate is produced by
11 preselecting said composite of said at least one polymer and said at
12 least one therapeutic substance, and said elastomer to give the
13 desired result.

14

15 60. The drug eluting stented graft of claim 53, wherein:

- 16 □ a multiplicity of microcapsules is dispersed within said at least one
17 polymer, wherein said microcapsules have a wall formed of a drug
18 release rate controlling material;
- 19 □ said at least one therapeutic substance is contained within said
20 multiplicity of microcapsules; and,
- 21
- 22 □ said at least one polymer has the formula:
- 23



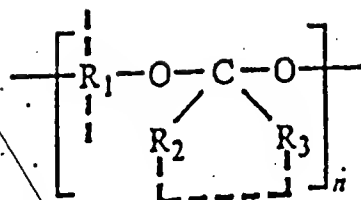
wherein R₁ is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene, and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons; R₂ and R₃ are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa; OR₁O with R₁ as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when R₂ and R₃ are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and alkenyl of 2 to 7 carbons formed

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1 when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12
2 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a
3 fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with
4 an alkyl of 1 to 7 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2
5 to 7 carbons; and wherein at least one of said R_2 and R_3 is a member
6 selected from the group consisting of alkoxy, alkenyloxy and OR_1O ; R_2
7 and R_3 when taken together are a member selected from the group of
8 heterocyclic and fused polycyclic rings having at least one oxygen atom in
9 the ring; and wherein n is greater than 10;
10 so that, in operation, said polymer and said microcapsules bioerode at a
11 controlled and continuous rate over a prolonged period of time, thereby releasing
12 said at least one therapeutic substance at a controlled and continuous rate over
13 a prolonged period of time.

14
15 61. The drug eluting stented graft of claim 53, wherein:

- 16 ☐ said coat further comprises at least a first layer and a second layer,
17 wherein said first layer comprises said at least one therapeutic
18 substance and at least a first polymer, and said second layer
19 comprises said at least one therapeutic substance and at least a
20 second polymer, wherein at least one of said first polymer and said
21 second polymer are selected from the group consisting of polymers of
22 the formula:
23



wherein R_1 is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons; R_2 and R_3 are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa; $O R_1 O$ with R_1 as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms

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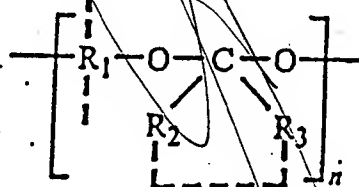
1 formed when R_2 and R_3 are taken together; a heterocyclic ring of
2 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7
3 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons
4 formed when R_2 and R_3 are taken together; a fused polycyclic
5 ring of 8 to 12 carbon and oxygen atoms formed when R_2 and R_3
6 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen
7 atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7
8 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said
9 R_2 and R_3 is a member selected from the group consisting of alkoxy, alkenyloxy
10 and OR_1O ; R_1 and R_3 when taken together are a member selected from the
11 group of heterocyclic and fused polycyclic rings having at least one oxygen atom
12 in the ring; and wherein is greater than 10;
13 so that when in operation, said layers bioerode at a controlled and continuous
14 rate over a prolonged period of time, thereby releasing said at least one
15 therapeutic substance at a controlled and continuous rate over a prolonged
16 period of time.

17
18 62. The drug eluting stented graft of claim 61, wherein said first polymer is a
19 pharmaceutically acceptable biocompatible non-bioerodible polymer that
20 sequesters an agent for brachytherapy.
21

63. The drug eluting stented graft of claim 62, wherein said agent for brachytherapy is selected from the group consisting of palladium-103 (^{103}Pd), ^{192}Ir , ^{32}P , ^{188}Re , and Sr/Y90 source trains.

64. The drug eluting stented graft of claim 53, wherein:

- a multiplicity of discrete, closed cells exists within said at least one polymer, said cells having a wall formed and defined by said at least one polymer;
- said at least one polymer has the formula:



wherein R₁ is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7

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carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons; R_2 and R_3 are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa; OR_1O with R_1 as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons formed when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said R_2 and R_3 is a member selected from the group consisting of alkoxy, alkenyloxy and OR_1O ; R_2 and R_3 when taken together are a member selected from the group of heterocyclic and fused polycyclic rings having at least one oxygen atom in the ring; and wherein n is greater than 10;

□ wherein said at least one therapeutic substance dissolved in a pharmaceutically acceptable carrier that is a solvent for said at least

one therapeutic substance and a nonsolvent for said at least one polymer is contained within said multiplicity of discrete, closed cells; so that, when in operation, said at least one polymer is capable of bioeroding at a controlled and continuous rate over a prolonged period of time, thereby releasing said at least one therapeutic substance at a controlled and continuous rate over a prolonged period of time.

65. The drug eluting stented graft of claim 53, wherein said stent comprises a plurality of elements, wherein each said element comprises an undulating linear shape formed into a generally cylindrical configuration having a cylinder axis generally aligned on the axis of said hollow bore, and wherein each said element is connected to an adjacent neighbor element by at least one linear connector.

66. The drug eluting stented graft of claim 65, wherein said plurality of elements comprises a spiral.

67. The drug eluting stented graft of claim 65, wherein at least one said connector is substantially circumferentially offset from an adjacent neighbor connector.

68. The drug eluting stented graft of claim 67, wherein said circumferentially offset connectors form a helical array.

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69. The drug eluting stented graft of claim 65, wherein at least one said connector is not substantially circumferentially offset from an adjacent neighbor connector.

70. The drug eluting stented graft of claim 65, wherein said undulating linear shape is a generally zigzag shape comprising a plurality of zigs having tips and a plurality of zags having tips, wherein said tip of each said zig of each element and the nearest said tip of each said zig of an adjacent neighbor element generally lie in a plane passing through the axis of said hollow bore, and wherein said tip of at least one said zig of each element and at least one said nearest said tip of a zig of an adjacent neighbor are connected by one said linear connector.

71. The drug eluting stented graft of claim 65, wherein said undulating linear shape is a sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein each said peak of each element and each said valley of an adjacent neighbor generally lie in a plane passing through the axis of said hollow bore, and wherein at least one said peak of each element and said valley of an adjacent neighbor lying generally in said plane are connected by one said linear connector.

72. The drug eluting stented graft of claim 65, wherein each said linear connector has a length dimension generally parallel to the axis of said hollow bore, and

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1 a width and depth dimension, and wherein said length dimension is greater
2 than said width dimension and said length dimension is greater than said
3 depth dimension.

4

5 73. The drug eluting stented graft of claim 72, wherein said length dimension is
6 about 3 to 10 times greater than said width dimension, and said length
7 dimension is about 3 to 10 times greater than said depth dimension.

8

9 74. The drug eluting stented graft of claim 53 wherein said PTFE is replaced by
10 an elastomer selected from the group consisting of fluorinated ethylene
11 propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer,
12 polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride;
13 and, other biocompatible plastics.

14

15 75. The drug eluting stented graft of claim 53 wherein said PTFE covering is
16 formed of expanded, sintered PTFE tape, said tape having been wound about
17 the outer surface of said stent to create said covering thereon.

18

19 76. The drug eluting stented graft of claim 53, wherein said PTFE is expanded
20 polytetrafluoroethylene having fibrils.

21

22 77. The drug eluting stented graft of claim 76, wherein said fibrils measure up to
23 about 300 μ in length.

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1

2 78. The drug eluting stented graft of claim 76, wherein said fibrils measure up to
3 about 200 μ in length.

4

5 79. The drug eluting stented graft of claim 76, wherein said fibrils measure up to
6 about 100 μ in length.

7

8 80. The drug eluting stented graft of claim 76, wherein said fibrils measure up to
9 about 50 μ in length.

10

11 81. The drug eluting stented graft of claim 76, wherein said fibrils measure up to
12 about 5 μ in length.

13

14 82. The drug eluting stented graft of claim 75 wherein said tape has a width of
15 less than about 1 inch (2.54 cm.).

16

17 83. The drug eluting stented graft of claim 75 wherein said tape has a thickness
18 of less than 0.015 inch (0.038 cm.) and wherein said tape is wound about
19 said stent in overlapping fashion, such that said elastomer covering
20 comprises 1 to 10 layers of said tape.

21

22 84. The drug eluting stented graft of claim 75 wherein said tape is helically
23 wrapped about said stent.

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1

2 85. The drug eluting stented graft of claim 75 wherein said tape has a width of 0.5
3 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8
4 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said drug
5 eluting stented graft.

6

7 86. The drug eluting stented graft of claim 75 wherein said tape is helically
8 wrapped alternately in a first direction and then in the opposite direction.

9

10 87. The drug eluting stented graft of claim 86 further comprising 8 layers of said
11 tape.

12

13 88. The drug eluting stented graft of claim 53 wherein said stent is a self-
14 expanding stent.

15

16 89. The drug eluting stented graft of claim 88, wherein said self-expanding stent
17 comprises a shape memory alloy that can alternately exist in a first and a
18 second crystalline state, wherein said stent assumes a radially expanded
19 configuration when said shape memory alloy is in said first crystalline state,
20 and a radially compact configuration when said shape memory alloy is in said
21 second crystalline state.

22

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1 90. The drug eluting stented graft of claim 53 wherein said stent is a pressure-
2 expandable stent.

3
4 91. The drug eluting stented graft of claim 88 wherein said stent is formed of a
5 metal alloy comprising at least two elements selected from the group
6 consisting of iron, cobalt, chromium, nickel, titanium, niobium, and
7 molybdenum.

8
9 92. The drug eluting stented graft of claim 89 wherein said shape memory alloy
10 comprises at least about 51% to about 59% nickel and the remainder
11 comprising titanium.

12
13 93. The drug eluting stented graft of claim 89 wherein said shape memory alloy
14 comprises about 0.25% chromium, at least about 51% to about 59% nickel,
15 and the remainder comprising titanium.

16
17 94. The drug eluting stented graft of claim 53 wherein said covering has a
18 thickness of less than 0.1 inch (0.25 cm.).

19
20 95. The drug eluting stented graft of claim 75 wherein said PTFE tape has a
21 thickness of less than 0.015 inches (0.038 cm.), said tape being wrapped
22 about said stent in overlapping fashion so as to form said covering.
23

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1 96. The drug eluting stented graft of claim 75 wherein said PTFE tape has a
2 density of less than 1.6 g/cc.

3
4 97. The drug eluting stented graft of claim 75 wherein said covering has a
5 thickness of less than 0.1 inch (0.25 cm.) and the PTFE tape has a density of
6 less than 1.6 g/cc.

7
8 98. The drug eluting stented graft of claim 53 wherein said coat was
9 applied to said stent by the steps of:

- 10 ☐ immersing said stent in a liquid polymer dispersion;
11 ☐ removing said stent from said liquid polymer dispersion; and,
12 ☐ drying said liquid polymer dispersion that has remained on said stent,
13 whereby said coat is formed on said stent.

14
15 99. The drug eluting stented graft of claim 53 wherein said coat is formed by
16 electron beam deposition.

17
18 100. The drug eluting stented graft of claim 53 wherein said tubular covering is
19 adherent to said coat.

20
21 101. A method for the treatment of cardiovascular disease, comprising
22 implanting the drug eluting stented graft of claim 53 in a patient in need of

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1 such treatment wherein said implantation is effective to ameliorate one or
2 more of the symptoms of said cardiovascular disease.

3

4 102. An article of manufacture, comprising packaging material and the drug
5 eluting stented graft of claim 53 contained within the packaging material,
6 wherein said drug eluting stented graft is effective for implantation in a patient
7 afflicted with cardiovascular disease, and the packaging material includes a
8 label that indicates that said device is effective for said implantation.

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